

11. (Amended) The delivery apparatus for a self-expanding stent according to claim 8, wherein the wire comprises stainless steel and has cross-sectional dimensions of 0.003 inches by 0.001 inches.

REMARKS

In response to the Final Office Action mailed March 11, 2003, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks in this Reply. Claims 1, 4, 8 and 11 were amended, no claims have been added, and claims 3 and 10 were cancelled without prejudice so that claims 1, 2, 4-9 and 11-15 remain pending. No new matter has been introduced.

Claims 1-2 and 6-7 were rejected as anticipated by U.S. Patent Number 6,425,898 to Wilson et al. (hereafter Wilson). This rejection is respectfully traversed.

Wilson discloses a delivery apparatus for a self-expanding stent. The delivery apparatus comprises a sheath, a shaft located coaxially within the sheath, a radiopaque fluid injection annular

gap and a self-expanding stent. The sheath includes a tubular member formed from an outer polymeric layer, an inner polymeric layer and a wire reinforcing layer.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention, as claimed in independent claim 1, is directed to a delivery apparatus for a self-expanding stent. The apparatus comprises a substantially tubular shaft and a substantially tubular sheath. The substantially tubular sheath having a proximal end, a distal end, and an enlarged section proximate the distal end. The sheath is coaxially positioned over the shaft such that the enlarged section is aligned with the stent bed of the shaft. The sheath includes an inner polymeric layer, an outer polymeric layer, and a reinforcement layer. The reinforcement layer comprises a flat wire having a substantially rectangular cross section.

Wilson fails to disclose or suggest "a reinforcement layer" comprising a flat wire having a substantially rectangular cross section as is claimed in independent claim 1. The flat wire of the present invention reduces the profile of the sheath without sacrificing strength or flexibility. Since Wilson fails to disclose or suggest a wire reinforcement layer having a substantially rectangular cross section, there can be no anticipation. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 3-5 were rejected as being unpatentable over Wilson in view of U.S. Patent Number 5,176,660 to Truckai (hereinafter Truckai). This rejection is respectfully traversed.

Truckai discloses a flexible catheter comprising at least one resilient tubular layer in telescoping relation with a tubular sheath made of helically disposed crossing strands. In one embodiment, the sheath comprises a braided structure in the form of a set of counter rotating helical strands. The strands may be flat. In another embodiment, the sheath comprises a mixture of flat strands and round strands.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d, 488, 20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Applicants respectfully submit that there is simply no motivation to modify the apparatus of Wilson based on the teachings of Truckai. Truckai teaches the use of wires or strands to form the sheath. In Truckai, the sheath is formed from the

wires or strands themselves. The sheath has no polymeric layers. As stated at column 3, lines 59-65, "Then an outer tubular layer 22 may be applied by extrusion over the braided tubular sheath 16, typically with some of the material of outer tubular layer 22 passing through the interstices of sheath 16 to enter into bonded relation with the material of inner tubular layer 12, to provide a strong, bonded catheter containing the desired sheath 16 of this invention." Accordingly, one can see that the catheter of Truckai comprises a sheath which is formed only from a braided strand structure. It would not have been obvious to modify Wilson's sheath with the sheath of Truckai because they are radically different types of structures. The present invention sheath comprises multiple layers of different materials, i.e. polymer, wire, polymer. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 8-15 were rejected as being unpatentable over Wilson in view of U.S. Patent Number 4,705,511 to Kocak (hereinafter Kocak). This rejection is respectfully traversed.

The present invention, as claimed in independent claim 8 is directed to a delivery apparatus for a self-expanding stent. The

apparatus comprises a shaft having a proximal end, a distal end, a guidewire lumen extending between the proximal and distal ends, and a stent bed proximate the distal end upon which the self-expanding stent is mounted, and a sheath defining an interior volume, the sheath having a proximal end, a distal end, and an enlarged section proximate the distal end, the sheath being coaxially positioned over the shaft such that the enlarged section is aligned with the stent bed, the sheath including an inner polymeric layer, a lubricious coating on the inner polymeric layer, an outer polymeric layer, and a reinforcement layer. The reinforcement layer comprising a flat wire having a substantially rectangular cross section.

Kocak discloses a flexible tube for the introduction of catheters and like devices into a vascular system. The tube comprises a helical coiled spring surrounded by a protective coating that defines a cylindrical wall. The protective coating is formed from a thermoplastic polymeric material including silicone polymers. The tube also comprises an interpolymer to act as a lubricious coating.

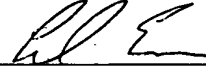
Applicants respectfully submit that the cited prior art references, whether taken alone or in combination, fail to disclose or suggest all of the claim limitations. Neither reference discloses a reinforcing layer comprising a flat wire having a substantially rectangular cross section. Applicants also respectfully submit that there is simply no motivation or suggestion to modify the apparatus of Wilson based on the teachings of Kocak. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicants would be willing to interview the present case if the Examiner so desires. Accordingly, the Examiner is invited to call the undersigned at (732) 524-2518 if such a call would facilitate the prosecution of this application.

The Reply/Amendment raises no new issues and places the application in form for allowance. Therefore, entry is proper and earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version With Markings To Show Changes Made."

Respectfully submitted,



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Version With Markings To Show Changes Made

IN THE CLAIMS

Please amend the claims as follows:

1. (Twice Amended) A delivery apparatus for a self-expanding stent comprising:

a substantially tubular shaft having a proximal end, a distal end, a guidewire lumen extending between the proximal and distal ends, and a stent bed proximate the distal end upon which a self-expanding stent is positioned; and

a substantially tubular sheath defining an interior volume, the sheath having a proximal end, a distal end, and an enlarged section proximate the distal end, the sheath being coaxially positioned over the shaft such that the enlarged section is aligned with the stent bed, the sheath [being formed from]including an inner polymeric layer an outer polymeric layer, and a [flat wire] reinforcement layer, the reinforcement layer comprising a flat wire having a substantially rectangular cross section.

Please cancel claim 3 without prejudice.

4. (Amended) The delivery apparatus for a self-expanding stent according to claim [3]4, wherein the wire comprises stainless steel and has cross-sectional dimensions of 0.003 inches by 0.001 inches.

8. (Twice Amended) A delivery apparatus for a self-expanding stent comprising:

a shaft having a proximal end, a distal end, a guidewire lumen extending between the proximal and distal ends, and a stent bed proximate the distal end upon which a self-expanding stent is mounted; and

a sheath defining an interior volume, the sheath having a proximal end, a distal end, and an enlarged section proximate the distal end, the sheath being coaxially positioned over the shaft such that the enlarged section is aligned with the stent bed, the sheath [being formed from]including an inner polymeric layer, a lubricious coating on the inner polymeric layer, an outer polymeric layer, and a [flat wire] reinforcement layer,the reinforcement layer comprising a flat wire having a substantially rectangular cross section.

Please cancel claim 10 without prejudice.

11. (Amended) The delivery apparatus for a self-expanding stent according to claim [10]8, wherein the wire comprises stainless steel and has cross-sectional dimensions of 0.003 inches by 0.001 inches.